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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 775,482	02 02 2001	Richard A. Shinkets	15966-577A CIP34 Cura-77	7782

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EXAMINER

ANDRES, JANET I

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02.10.2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,482

Applicant(s)

SHIMKETS ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-14,16-21 and 23-47 is/are pending in the application.
- 4a) Of the above claim(s) 27-47 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-7,9-14 and 16-19 is/are allowed.
- 6) ☒ Claim(s) 20, 21, 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 27 November 2002 is acknowledged. Claims 1, 3-7, 9-14, 16-21 and 23-47 are pending in this application. Claims 27-47 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to the specification is withdrawn in response to Applicant's amendment.
3. The rejection of claims 1-26 under 35 U.S.C. 112, second paragraph, as indefinite, is withdrawn in response to Applicant's amendment.
4. The rejection of claims 1-19 under 35 U.S.C. 102(e) as anticipated by WO 01/00878, WO 00/66736, and WO 00/27879 is withdrawn in response to Applicant's arguments.

Claim Rejections Maintained

5. The rejection of claims 20, 21, and 23-26 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained for reasons of record in the office action of paper no. 9.

Applicant argues that differential expression is shown in Example 7. Applicant further argues that differential serum concentration is shown in Example 37. Applicant states that it would be routine to obtain or determine the stages of these cancers. Applicant additionally argues that, in Example 36, the samples are taken from subjects at various stages in disease progression. Applicant states that the example indicates that a range of concentrations that may be considered characteristic of each stage is determined. Applicant states that no experimentation is required, merely the performance of the assays. Applicant further argues that the specification teaches techniques for staging.

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Applicant's arguments have been fully considered but have not been found to be persuasive. As stated on p. 4 in the previous office action, no correlation of protein levels with disease progression is shown. What is shown in examples 7 and 37 is that some cancers express the antigen. While one of skill could determine the stage using other methods, one of skill would not be able to predict, based on Applicant's disclosure, what antigen levels would be correlated with disease progression and use the instant method to stage cancers. That an ELISA is described in Example 36 is further not sufficient guidance to allow one of skill in the art to predictably correlate the level of antigen expression with the stage of any cancer. Applicant has provided no guidance or teachings predictive of a successful outcome: there is nothing in the specification that would allow the skilled artisan to predict that antigen levels were correlated with disease progression. The specification merely correlates antigen levels with the presence or absence of cancer, not the stage. Although the specification outlines art-recognized procedures determining antigen levels, this is not adequate guidance as to how antigen levels could be used to stage any cancer, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. What is provided is thus the idea for an invention, and the invitation to experiment to implement this invention, not the invention itself.

CLAIMS 1, 3-7, 9-14, AND 16-19 ARE ALLOWED. CLAIMS 20, 21, AND 23-26 ARE REJECTED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

January 29, 2003


J. FYLEN, PH.D.
PATENT EXAMINER
ART UNIT 1600